



Securing the Future of Neuromodulation: Class III Implant with Cybersecurity

Helping a MedTech Leader Launch a Next-Gen Implantable System with Secure Communication and Reliable Firmware

OVERVIEW

Digital Health Solutions partnered with a leading developer of Class III neuromodulation systems to enhance the security and regulatory readiness of their next-generation implantable platform. Our role spanned the entire development lifecycle from requirements generation to embedded firmware and tablet software development, secure communication architecture, testing, and compliance documentation. By aligning with Class III standards and cybersecurity best practices, we enabled a smooth pathway toward FDA clearance.

CHALLENGES

- **Secure Communication Implementation:** Designing a cryptographically secure link between the implant and clinician programmer.
- **Hardware-Based Security:** Integrating a secure element and microcontroller that supports modern cybersecurity needs.
- **Regulatory Compliance:** Delivering verifiable firmware features within Class III constraints (IEC 62304, FDA guidance).
- **Accelerated Timelines:** Executing a complex architecture update under tight deadlines for launch readiness.

IMPACT

- **Enhanced Security Foundation:** Delivered hardware-rooted trust and encrypted communication for regulatory-grade safety.
- **Accelerated Development Cycles:** Reduced iteration time via robust documentation, test tooling, and CI integration.
- **Regulatory Readiness:** Provided a complete software package aligned with IEC 62304 and FDA cybersecurity requirements.
- **Future-Proof Platform:** Equipped the client with scalable tools and processes to support ongoing updates and third-party audits.

APPROACH

- **Full-System Engineering:** Authored lifecycle documentation and traceability matrices to meet IEC 62304 and FDA expectations.
- **Secure Software Architecture:** Led development of secure bootloaders, firmware, and host-side software using public key infrastructure.
- **Advanced Cryptography:** Built a custom encrypted communication protocol with mutual authentication and key rotation.
- **Automated Testing & CI:** Integrated unit and system-level test frameworks with CI/CD pipelines for rapid validation.

About Digital Health Solutions

DHS, located near Boston, MA, provides key engineering, testing, documentation & regulatory services for Medical Device, Diagnostics, Healthcare and Life Science industries. Our expertise & services include:

- **End-to-end Product Development**
- **Firmware/Software Engineering (AI/ML)**
- **Systems Engineering**
- **Quality & Regulatory Guidance**
- **Cybersecurity**
- **ISO 13485 Contract Manufacturing**
- **Verification and Validation Testing/Documentation**

Accelerating MedTech Innovation

Let's build something together.

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